

On May 11, 2015, at 11:14 AM, Andrew Cohen <[acohen@bioinvasions.com](mailto:acohen@bioinvasions.com)> wrote:

May 11, 2015

Deborah Nagle  
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U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

(via email)

Dear Ms. Nagle,

I'm writing regarding Judy Meyer's April 26 letter to you, about the report produced by the 2011 SAB Panel on Ballast Water.

Last year Fred Dobbs and I, who had been members of the 2011 Panel, realized that a major conclusion of the Panel report was incorrect, and that it was contradicted by the very data that the Panel had relied on. Specifically, the report concluded that when the test data that had been determined by the Panel to be reliable was assessed by the method described in the report, five types of ballast water treatment systems met the IMO D-2 ballast water discharge standard, but none met the 10x IMO D-2 standard. However, when we examined the test data we found that out of the nine treatment systems whose data the Panel had determined were reliable, three treatment systems had consistently produced organism concentrations that were below the limits in the 10x IMO D-2 standard. In short, we found that when the test data that the Panel determined was reliable was assessed by the method described in the report, it was impossible to reach the conclusion that was given in the report.

We summarized our analysis as clearly as we could and on February 2nd sent this summary, along with the actual test data, to the other former Ballast Water Panel members. (I'm attaching this letter and supplemental material, which were not previously sent to you; additional documentation is available at the URL given in the letter.) After some discussion, six former Panel members, including Fred and myself, wrote the EPA Administrator pointing out the error and requesting that it be corrected (that letter was cc'd to you).

In five bullet points, Judy's letter summarized comments made by four former Panel members. The rest of the 14 (not 16) former Panel members who declined to sign the letter gave a variety of reasons, though several simply indicated that they didn't feel it was constructive to revisit these old issues, or that time would be better spent on a new study. Of the five bullet points in Judy's letter, the first states a concern that the discussion was not sufficiently public, and the fifth says that a new study should be done. However, bullet points 2, 3 and 4 appear to be critical of our finding that the report's conclusion was in error, and I will address these.

Bullet Point 2 is a close paraphrase of comments in an email from two members of the Panel subgroup that had determined which test data were reliable and had conducted the analysis that

produced the incorrect conclusion. These comments, and Judy's paraphrase, suggest that Fred and I based our assessment on data that was produced without proper QA/QC procedures and transparency, and which was therefore unreliable. However, as we stated above, and also stated repeatedly in our communications with the former Panel and in the materials sent to the Administrator, our finding that there was an error was based on the test data that had been determined to be reliable by the Panel (that is, by the subgroup of the Panel that included these two commenters). Specifically, we found that the Ecochlor, Severn Trent De Nora BalPure and SEDNA PeraClean treatment systems yielded test results that consistently met the 10x IMO D-2 standard, and we included the actual test results in the material sent to the former Panel members and Administrator. If you look at Appendix A of the Final SAB Report, you will see that the test reports for the Ecochlor, BalPure and PeraClean systems—the reports from which we took the results that our assessment is based on—are all shaded, and the Appendix states: "Shaded rows indicate those documents that the Panel used as reliable sources of credible data for their assessment." In Table 4-1 of the report, you will similarly find that the only treatment system considered by the Panel that used Filtration & Chlorine Dioxide (= Ecochlor), two treatment systems that used Filtration & Electrochlorination (including BalPure), and the only treatment system that used Hydrocyclone, Filtration & Peracetic Acid (= PeraClean), are all listed as having reliable data (4th column in the table; the treatment processes used by the systems are listed after the treatment system names in Appendix A).

The tests of the Ecochlor, BalPure and PeraClean treatment systems were conducted at two established, respected laboratories, the Royal Netherlands Institute for Sea Research (known by the acronym NIOZ), and the Maryland Environmental Research Center (MERC) on Chesapeake Bay. The test reports (which are available at the URL listed in our letter to the Panel and in the EPA docket) all refer to the QA/QC procedures that were used and reference the following documents for further details:

*NIOZ. 2009. Test protocols and Quality Assurance Project Plan (QAPP) for the efficacy testing of the Ecochlor® Ballast Water Treatment System (Ecochlor, Inc) as part of the type approval process under Resolution MEPC 125.53.*

*NIOZ. 2009. Test protocols and Quality Assurance Project Plan (QAPP) for the efficacy testing of the BalPure® Ballast Water Treatment System (STDN, LLC) as part of the type approval process under Resolution MEPC 125.53 and MEPC 174.58.*

*MERC. 2009. Test Plan for the Performance Evaluation of the Severn Trent De Nora BalPure BP-1000 Ballast Water Management System.*

*NIOZ. 2007. Test protocols for the biological efficacy testing of the Hamann Ballast Water Treatment installation (SEDNA®-System) as part of the type approval process under resolution MEPC 125.53.*

In short, the statement in Judy's second bullet point and in the earlier email from which it was taken, that most facilities did not have a quality management system and that the data produce by them cannot be considered reliable, might be true. But true or not, it is not relevant to our assessment, which was based only on the test data and test reports that the commenters themselves determined to be reliable, derived from tests conducted by established laboratories that published detailed descriptions of the quality management systems used in those tests.

Bullet Point 3 is a not-quite-accurate paraphrase of a further comment in the same paragraph from the same email as the Bullet Point 2 comment, which it directly follows. The comment in the email from the two former panel members refers to inadequacy or lack of validation of the sampling approaches, sample volumes and some analytical methods used "in initial TA testing" and "in prior TA testing." Judy's bullet point instead states that "the testing data available to the panel" used methods and volumes that had been deemed inadequate or were not validated. This is not what the two former Panel members said and can't be what they meant, since they themselves had determined that for nine treatment systems "the testing data available to the panel" were reliable. In any event, as noted above, our analysis was based only on the testing data that the Panel and subgroup had determined were reliable.

The bullet point (and the comment in the original email) goes on to say that one cannot conclude that a system met one or another standard based on a series of zeros in the results without considering the detection limits. I agree completely. In the attachments to our Feb. 2 letter to former Panel members and our Mar. 2 letter to the EPA Administrator, we provided both the test data for the Ecochlor, BalPure and PeraClean systems and our assessment of those data. Wherever the results consisted of a string of zeros or non-detects, we reported the detection limits, and we based our assessment on those detection limits.

Bullet Point 4 is a close paraphrase of a comment in an email from another former member of the Panel. It states that the data available to the panel were generated with IMO test methods, which don't provide "the precision to discern a difference between meeting 1X and 10X the D-2 standard." If this were in fact true, then one could never determine on the basis of data generated with IMO test methods that a treatment system met IMO D-2 but not 10x IMO D-2. Thus, it would have been impossible for the Panel to conclude that five treatment types met IMO D-2 but none met 10x IMO D-2. That conclusion is incorrect, because that's not what the data show, but it's not inherently impossible to reach such a conclusion based upon IMO test data, as the original comment and Judy's bullet point claim. For example, both the Panel's initial analysis and our later analysis found that the test data, generated with IMO methods, for three treatment types (Deoxygenation & Cavitation, Filtration & UV, and Filtration, UV & TiO<sub>2</sub>) met the IMO D-2 standard but did not meet the 10x IMO D-2 standard. (The Panel's analysis and our later analysis disagree about the other three treatment types for which there were reliable data, to which the Ecochlor, BalPure and PeraClean systems belong.)

So, what does this comment even mean? I'm not sure, but I suspect the commenter meant to assert that IMO generated data would provide sufficient certainty that a discharge meets IMO D-2 if the sample tested is shown to meet IMO D-2, but would not provide sufficient certainty that a discharge met 10x IMO D-2 even if the sample tested met 10x IMO D-2 (this certainty issue is what's discussed in the statistics section of the EPA report on ballast water analysis, *Density Matters*). First, as described in our Feb. 2 letter to the former Panel members, the methods described in the Panel report do not mention, and are not consistent with, the use of a test to accept or reject sample results based on a required level of statistical certainty. Second, however, there is no possible level of statistical certainty that would support the Panel's erroneous conclusion (this finding—verified by Loveday Conquest, who chaired the subgroup that wrote the statistics

chapter for the Panel report—is discussed in the Feb. 2 letter and developed in the analysis posted at the listed URL).

In summary, no actual flaw in our analysis was raised by any of these comments, and at the same time no one has shown how it would be possible to reach the report's conclusion using the methods the Panel reported and the data the Panel relied on. The issue is not insignificant. The report's erroneous conclusion was cited as the basis for adopting the IMO D-2 discharge limits in the EPA's Vessel General Permit (*VGP Fact Sheet*, pp. 74-75 (2013)) and for adopting the same limits in USCG's ballast water discharge standards under the National Invasive Species Act (*Federal Register* 77(57): 17256 (March 23, 2012)). Discharge standards based on erroneous conclusions put environmental quality and public health at unnecessary risk. EPA should assess and correct the error in the report; and both EPA and USCG should reconsider the discharge standards that they adopted based on the report's erroneous conclusion.

Several former Panel members recommended that a new study be conducted using the latest available test data. I agree that such a study, *if properly done*, would be worthwhile. However the previous study, from conception to EPA action on the results, took about four years. Planning for a new study is no substitute for acting now to correct an erroneous conclusion that we know about, and which is the basis for current U.S. policy.

Sincerely,

Andrew Cohen

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